

3  
B assemblies, forming an array of syringe barrel assemblies in said at least one housing assembly, placing said array in a container and closing said container.

Please delete claim 2 without prejudice or disclaimer.

#### REMARKS

By this amendment, applicants have amended claims 1 and 20, and canceled claim 2. Thus, claims 1 and 3-40 remain pending in the present application.

In the Office Action, the Examiner has rejected claims 1-40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,189,292. In response thereto, applicants submit, concurrently herewith, a terminal disclaimer in compliance with 37 CFR §1.321(c).

In the Office Action, the Examiner has also noted that one or more conditions for receiving the benefit of an earlier priority date under 35 U.S.C. §§ 119(e) and 120 have not been met. In response thereto, applicants have amended the specification to include a specific reference to each prior application to which the subject application claims priority.

The Examiner has rejected claim 2 under 35 U.S.C. §112, first paragraph, as containing subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. Specifically, the Examiner has taken the position that the specification does not disclose the container being sterilized after being enclosed in a second container. Applicants respectfully direct the Examiner's attention to page 6, line 19-24 of the specification, where it is disclosed that "A further object of the invention is to provide a housing assembly which maintains a locally controlled environment for assembling medical containers and packaging an array of medical containers in closed second containers. The medical containers can be sterilized in a subsequent step." Applicants

respectfully submit that page 17, lines 17-20, page 27, lines 8-11, page 28, lines 17-19, page 31, lines 11-16, and FIG. 9 also disclose that aspect of applicants' invention. Thus, applicants respectfully submit that the specification does contain the disclosure noted by the Examiner to be lacking, satisfying the requirements of 35 U.S.C. §112, first paragraph. Consequently, applicants submit that the Examiner's rejection of claim 2 under 35 U.S.C. §112, first paragraph, is no longer tenable and respectfully request withdrawal of that rejection.

In the Office Action, the Examiner has also rejected claims 20-29 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicants regard as the invention. In view of the amendment made to claim 20 herein, applicants respectfully submit that the Examiner's rejection of claims 20-29 under 35 U.S.C. §112, second paragraph, is no longer tenable, and respectfully request withdrawal of that rejection.

The Examiner has also rejected claims 1-18, 33-34 and 37-38 under 35 U.S.C. §102(a) as being anticipated by U.S. Patent No. 5,687,542 to Laweck et al. Applicants respectfully traverse that rejection. Laweck et al. is directed to an apparatus and method for manufacturing articles, such as syringe barrels, substantially free from contaminants. However, Laweck et al. fails to teach or suggest enclosing the container in a second container and sterilizing the container, as now recited by applicants' amended claim 1. Applicants respectfully submit that Laweck et al. fails to teach or suggest every limitation recited by applicants' claims, as required of a proper 35 U.S.C. §102 reference. Thus, applicants further respectfully submit that their invention, as recited by claims 1-18, is not anticipated under 35 U.S.C. §102(a) by Laweck et al., and request that the Examiner withdraw that rejection.

Applicants' claims 33 and 37 recite, *inter alia*, delivering a tip cap to the environmentally controlled area and air cleaning the tip cap in the environmentally controlled area. Applicants respectfully submit that Laweck et al. does not teach or suggest that limitation. In contrast,

Lawecki et al. only teaches applying a lubricant to a tip seal. Column 8, lines 22-25. Applicants respectfully submit that such a disclosure does not anticipate their invention, as recited by claim 33. Moreover, applicants further respectfully submit that Lawecki et al.'s disclosure of applying a lubricant to a tip seal teaches away from applicants' recited step of air cleaning a tip cap; the Lawecki et al. teaching applying something to the tip seal, and applicants' step removing something from the tip cap. Thus, applicants respectfully submit that their invention, as recited by claims 33-34 and 37-38 is not anticipated under 35 U.S.C. §102(a) by Lawecki et al., and request that the Examiner withdraw that rejection.

Applicants thus respectfully submit that Lawecki et al. fails to teach or suggest each limitation recited by claims 1-18, 33-34 and 37-38. Consequently, those claims are not anticipated under 35 U.S.C. §102(a) by Lawecki et al. Applicants respectfully request that the Examiner withdraw the rejection of those claims.

In the Office Action, the Examiner has also rejected claims 3 and 10-11 under 35 U.S.C. §103(a) as obvious over Lawecki et al. in view of U.S. Patent No. 4,521,237 to Logothesis. Applicants respectfully traverse that rejection. The Examiner has taken the position that the deficiencies in the disclosure of Lawecki et al. are overcome by the disclosure of Logothesis. Specifically, that Logothesis discloses a method for forming a glass syringe barrel heated to an annealing temperature. In view of that disclosure, the Examiner believes that it would have been obvious to a person of ordinary skill in the art to modify the invention of Lawecki et al. by adding a glass forming station, as taught by Logothesis. However, in view of the remarks provided above with regard to claims 1-18 and the failure of Lawecki et al. to teach or suggest all limitations recited by those claims, applicants respectfully submit that the Examiner's proposed combination of Lawecki et al. and Logothesis does not render applicants' invention obvious. Specifically, the Examiner's proposed combination would still not teach or suggest enclosing the container in a second container and sterilizing the container, as recited by applicants' claims.

Thus, applicants respectfully submit that the Examiner's rejection of claims 3 and 10-11 as obvious over Lawecki et al. in view of Logothesis is no longer tenable and request withdrawal of that rejection.

In the Office Action, the Examiner has also rejected claims 7, 15 and 33 under 35 U.S.C. §103(a) as obvious over Lawecki et al. in view of U.S. Patent No. 4,628,969 to Jurgens, Jr. et al. Applicants respectfully traverse that rejection. The Examiner has taken the position that the deficiencies in the disclosure of Lawecki et al. are overcome by the disclosure of Jurgens, Jr. et al. Specifically, that Jurgens, Jr. et al. discloses a process for producing a prefilled plastic syringe. In view of that disclosure, the Examiner believes that it would have been obvious to a person of ordinary skill in the art to modify the invention of Lawecki et al. by having the steps of prefilling, as taught by Jurgens, Jr. et al. However, in view of the remarks provided above with regard to claims 1-18 and 33-34, and the failure of Lawecki et al. to teach or suggest all limitations recited by those claims, applicants respectfully submit that the Examiner's proposed combination of Lawecki et al. and Jurgens, Jr. et al. does not render applicants' invention obvious. Specifically, the Examiner's proposed combination would still not teach or suggest enclosing the container in a second container and sterilizing the container, as recited by applicants' claims. Thus, applicants respectfully submit that the Examiner's rejection of claims 7, 15 and 33 as obvious over Lawecki et al. in view of Jurgens, Jr. et al. is no longer tenable and request withdrawal of that rejection.

In the Office Action, the Examiner has also rejected claim 37 under 35 U.S.C. §103(a) as obvious over Lawecki et al. in view of U.S. Patent No. 5,597,530 to Smith et al. Applicants respectfully traverse that rejection. The Examiner has taken the position that the deficiencies in the disclosure of Lawecki et al. are overcome by the disclosure of Smith et al. Specifically, that Smith et al. discloses a process for producing a prefilled plastic syringe. In view of that disclosure, the Examiner believes that it would have been obvious to a person of ordinary skill in

the art to modify the invention of Laweck et al. by having the steps of filling, as taught by Smith et al. However, in view of the remarks provided above with regard to claims 37-38, and the failure of Laweck et al. to teach or suggest all limitations recited by those claims, applicants respectfully submit that the Examiner's proposed combination of Laweck et al. and Smith et al. does not render applicants' invention obvious. Thus, applicants respectfully submit that the Examiner's rejection of claim 37 as obvious over Laweck et al. in view of Smith et al. is no longer tenable and request withdrawal of that rejection.

In the Office Action, the Examiner has also rejected claims 19-32 under 35 U.S.C. §103(a) as obvious over Laweck et al. in view of Logothesis. Applicants respectfully traverse that rejection. The Examiner has taken the position that Laweck et al. discloses all limitations recited by claim 19 except for the detailed process of forming a glass syringe. The Examiner suggests that that deficiency is overcome by the disclosure of Logothesis. However, applicants respectfully note that neither Laweck et al. nor Logothesis teach or suggest annealing a glass syringe barrel at a temperature of at least 500 °C, as recited by applicants' claim 19. Applicants further respectfully submit that the disclosure of Laweck et al. that any process for forming a container that generates enough heat to render an article substantially free of contaminants does not teach or suggest applicants' invention. Applicants further note that neither Laweck et al. nor Logothesis teach or suggest annealing the syringe barrels, and thereafter, immediately transferring the syringe barrels to a housing assembly for maintaining a predetermined cleanliness level, as recited by applicants' claim 19. Applicants find no teaching in Laweck et al., Logothesis, or any other prior art reference of record in the subject application that teaches or suggest the invention recited by applicants' claim 19. Thus, applicants respectfully submit that the Examiner's rejection of claims 19-32 as obvious over Laweck et al. in view of Logothesis is no longer tenable and request withdrawal of that rejection.

In the Office Action, the Examiner has also rejected claims 35-36 under 35 U.S.C. §103(a) as obvious over Lawecki et al. in view of Jurgens, Jr. et al. Applicants respectfully traverse that rejection. Claims 35 and 36 each depend directly from claim 33. In view of applicants' remarks set forth above with regard to the deficiencies of Lawecki et al. and claims 33-34, and the failure of Lawecki et al. to teach or suggest all limitations recited by those claims, applicants respectfully submit that the Examiner's proposed combination of Lawecki et al. and Jurgens, Jr. et al. does not render the invention recited by claims 35-36 obvious, and applicants respectfully request withdrawal of that rejection.

In the Office Action, the Examiner has also rejected claims 39-40 under 35 U.S.C. §103(a) as obvious over Lawecki et al. in view of Smith et al. Applicants respectfully traverse that rejection. Claims 39 and 40 each depend directly from claim 37. In view of applicants' remarks set forth above with regard to the deficiencies of Lawecki et al. and claims 37-38, and the failure of Lawecki et al. to teach or suggest all limitations recited by those claims, applicants respectfully submit that the Examiner's proposed combination of Lawecki et al. and Smith does not render the invention recited by claims 39-40 obvious, and applicants respectfully request withdrawal of that rejection.

In view of the amendments set forth herein and the remarks provided above, applicants respectfully submit that claims 1 and 3-40 are in condition for allowance, and respectfully request that the Examiner earnestly reconsider his objections and rejections of the present application.

Changes to the Specification and Claims in accordance with this amendment are indicated on the pages entitled Version To Show Changes Made To The Specification And Claims.

Applicants hereby authorize the Commissioner to charge the fees necessary in connection with this amendment and the concurrently filed Petition for Extension of Time, and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicants.

Respectfully submitted,

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**VERSION TO SHOW CHANGES MADE TO THE SPECIFICATION AND CLAIMS**

Changes to the specification and claims in accordance with this amendment are indicated below.

**IN THE SPECIFICATION**

This application claims the benefit ~~under 35 U.S.C. § 119(e)~~ of U.S. ~~provisional application~~ Provisional Patent Application Serial No. 60/077,897 filed March 13, 1998 ~~and 1998~~, U.S. ~~provisional application~~ Provisional Patent Application Serial No. 60/102,338 filed September 29, 1998, U.S. Patent Application Serial No. 09/267,107 filed March 12, 1999, now U.S. Patent No. 6,189,292, and U.S. Patent Application Serial No. 09/678,080 filed October 3, 2000, now U.S. Patent No. 6,263,641, which are hereby incorporated by reference in their ~~entirety~~ respective entireties.

**IN THE CLAIMS**

1. A method producing a container comprising the steps of:  
forming a container in a forming device,  
  
transferring said container to an environmentally controlled area to maintain a predetermined cleanliness level, ~~and~~  
  
cleaning said container;
- ~~2. The method of claim 1, further comprising:~~  
  
enclosing said container in a second container, and  
  
sterilizing said container.



20. The method of claim 19, further comprising coupling at least one syringe component to said syringe barrels to form a plurality of syringe barrel assemblies, forming an array of syringe barrel assemblies in said at least one housing assembly, placing said array in a container and closing said container ~~to form said syringe barrel assemblies.~~